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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/634,082	08/08/2000	Keith D. Beaty	47168-00068USC1	5448
7.	590 09/14/2004		EXAMINER	
Daniel J. Burn			WOO, JU	LIAN W
JENKENS & C 1445 Ross Ave	GILCHRIST nue Suite 3200		ART UNIT	PAPER NUMBER
Dallas, TX 75202-2799			3731	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	09/634,082	BEATY, KEITH D.	\mathbb{Q}_{ℓ}
Office Action Summary	Examiner	Art Unit	
	Julian W. Woo	3731	
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet with the c	correspondence addre	SS
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a re If NO period for reply is specified above, the maximum statutory perior Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tin ply within the statutory minimum of thirty (30) day of will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this commi	unication.
Status			
1) Responsive to communication(s) filed on <u>21</u>	<u>June 2004</u> .		
2a)⊠ This action is FINAL . 2b)□ Th	is action is non-final.		
3) Since this application is in condition for allow	ance except for formal matters, pro	osecution as to the me	erits is
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.	
Disposition of Claims			
4) Claim(s) 90-120 and 122-142 is/are pending	in the application.		
4a) Of the above claim(s) is/are withdr	awn from consideration.		
5) Claim(s) <u>106-109,116-120,122-127,131-136</u>	and 139-142 is/are allowed.		
6) Claim(s) 90-95,97-104,110-115,128-130,137	and 138 is/are rejected.		
7)⊠ Claim(s) <u>96</u> is/are objected to.			
8) Claim(s) are subject to restriction and	or election requirement.		
Application Papers			
9) The specification is objected to by the Examin	ner.		
10) The drawing(s) filed on is/are: a) a		Examiner.	•
Applicant may not request that any objection to the			
Replacement drawing sheet(s) including the corre			l.121(d).
11) The oath or declaration is objected to by the I		•	
Priority under 35 U.S.C. § 119			
	en neigeitu undar 25 II C.O. C 440/a) (d) an (f)	
12) Acknowledgment is made of a claim for foreign	gn phonty under 35 U.S.C. § 119(a)-(a) or (i).	
a) All b) Some * c) None of:	nta haya baan rasaiyad		
1. ☐ Certified copies of the priority docume		! \ -	
2. Certified copies of the priority docume			
3. ☐ Copies of the certified copies of the pr	•	ed in this National Sta	ge
application from the International Bure			
★ See the attached detailed Office action for a list	st of the certified copies not receive	ea.	
Attachment(s)	, -	(DTO 446)	
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview Summary Paper No(s)/Mail D		
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0	8) 5) 🔲 Notice of Informal F	Patent Application (PTO-15	2)
Paper No(s)/Mail Date	6) 🔲 Other:		

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 137 and 138 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 137, "bone tissue," an unpatentable part of the human body, is claimed as a structural part of the invention (i.e., "...said screw-type dental implant is threadably installed in said bore...").

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 90-95 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by 4. Balamuth (Re. 28,752). Balamuth discloses, in figures 1 and 10 and in col. 9, line 18 to col. 11, line 68, a device having an osteotome or compaction tool (165b) with a lower end, an upper end, an outer surface, and a central axis entirely within the outer surface between the upper end and the lower end, a driving mechanism (65b) with a piezoelectric transducer element and a cone-shaped mechanical coupling component (70b), a power source (through 46), coupling means (180b) with means for releasing and attaching the tool to the driving mechanism, vibrational motion is the direction of the central axis (see col. 10, lines12-24), a drive rod (65b) between the piezoelectric transducer and the coupling means, a tool segment with a constant cross-section (at 75b), and a coupling means with a screw element (thread) extending into the tool. Note: The introductory statement of intended use ("for developing a bore in living bone for receiving a screw-type dental implant") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Balamuth et al., which is capable of being used as claimed if one desires to do SO.

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Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 6. Claims 98-100, 102, 103, 124-125, and 137-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn (6,139,320). Hahn discloses the invention substantially as claimed. Hahn discloses in figures 1 and 13 and in col. 2, lines 21-26; col. 4, lines 12-19; and col. 16, lines 53-59; a compaction tool and a method for developing an elongated bore in a living bone (150), where the method includes the application of an osteotome or compaction tool (154) or a tool, a driving mechanism (16) with a piezoelectric transducer element and vibrational motion (see col. 12, lines 43-45); and where the tool includes a central axis, a sequence of regions from the lower end to the upper end that increases in cross-sectional area or is tapered (at the spherical portion), and regions of constant diameter (152). Hahn also discloses that the geometry of the cavities is a result of the geometric form of the tools forming the cavities (i.e., the length and width dimension of a formed, elongated bore is defined by the tool). However, Hahn does not disclose installing an implant into the elongated bore, where the implant has length corresponding to the length of the elongated bore. Nevertheless, Hahn also discloses, in col. 1, lines 8-20 that bone replacement material (i.e., materials

which can also be used as dental implants with surfaces), is applied in bone cavities formed by work tools, where the material filling a cavity or bore (i.e., an implant) inherently has a length corresponding to the length of the bore. Therefore, it would be obvious to one having ordinary skill in the art to apply bone replacement material to a bone bore that is modified by Hahn's tool. Such an implant would replace weakened or diseased bone removed and displaced by Hahn's tool.

Hahn also does not disclose an osteotome tool engaging living bone substantially along an entire length of a bore in the bone, the tool incrementally compacting bone, and the step of developing a pilot hole before insertion of the tool in the hole.

Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to engage the tool along the length of the bore. Such a practice would be applied, if upon necessity, a bore is formed that is large enough to accommodate a substantial portion of the tool. Also, formation of the bore inherently causes some compaction of bone material by the tool, so incremental formation of the bore would lead to incremental compaction of the living bone. It would also be obvious to develop a pilot hole before insertion of a tool. A pilot hole would allow positionally precise boring into bone through guidance of the tool along the axis of the hole.

7. Claims 101,104, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Idemoto et al. Hahn discloses the invention substantially as claimed, but does not disclose a method where the piezoelectric transducer element oscillates when electrical oscillations of a selected frequency and amplitude are produced by electric power and where vibrational motion of the tool has a

frequency of 500 Hz. Idemoto et al. teach, in col. 3, lines 37-60, transducer element oscillations from electrical oscillations produced by electric power and variable vibrational motion frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Idemoto et al., to control the transducer element oscillations via control of electrical power frequencies and choose a vibrational motion frequency of 500 Hz. Such control of transducer element oscillations and the choice of a vibrational motion frequency would be applied according to conditions of the operation to be performed, including for example, tissue hardness.

- 8. Claims 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Comeaux (5,151,030). Hahn discloses the method for developing an elongated bore in a living bone substantially as claimed, but does not disclose using a power-driven mechanism to install the dental implant into the elongated bore. Comeaux teaches, in the figures, a power-driven mechanism (10) for the installation of filling material (dental implant) into a bore (see also col. 4, lines 3-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Comeaux, to apply a power-driven mechanism to install an implant as disclosed by Hahn. Such a mechanism would spread, compact, and shape the implant to a desired configuration within a bore.
- 9. Claim 127-130 are rejected under 35 U.S.C. 103(a) as being unpatentable over Idemoto et al. Idemoto et al. disclose the invention substantially as claimed. Idemoto et al. disclose, in figure 1, cutting edges (23, 24, and 25) being generally perpendicular to

the central axis of the tool, but do not disclose a method with a tool having a vibrational motion frequency of about 500 Hz and where the cutting edge develops the bore, while the central axis of the tool is generally perpendicular to the bone adjacent to the bore. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to choose such a frequency. Such a choice would be dependent upon conditions of the operation to be performed, including for example, tissue hardness. A choice of 500 Hz would be useful for cutting soft tissue without undue damage to the tissue. Also, it would be a matter of design choice in the development of a bore for the central axis of the tool to be generally perpendicular to the bone adjacent to the bore. The choice would be dependent upon the angle of the tool necessary for removing selected portions of bone in order to achieve a desired size and shape of the bore.

Allowable Subject Matter

- 10. Claims 106-109, 116-120, 122, 123-127,131-136, and 139-142 are allowed.
- 11. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a device for developing in living bone an elongated bore that includes, inter alia, a compaction tool and a driving mechanism with means for vibrationally moving the tool, where the tool has bone-engaging surface having depth markings; and method of installing a dental implant into a bore in living bone, where the method includes developing the bore with an ostetome tool having piezoelectric transducer element as a driving mechanism and where a dental implant in screwed into the bore. None of the prior art of record, alone or in

combination discloses, a dental system with, inter alia, a screw-type dental implant and an ostetome tool having a cutting edge and a bone-compacting surface and a piezoelectric transducer element as a driving mechanism.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

- 12. Claim 96 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 13. Claim 137 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
- 14. Claim 138 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- 15. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an osteotome tool having, inter alia, a cross-section that increases from a lower end to an upper end, where the tool also has depth markings between the lower end and the upper end. Also, the prior art of record, alone or combination, discloses a set of components with, inter alia, a screw-type dental implant, a compaction tool, and a vibrational driving mechanism for the tool.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not

complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

16. Applicant's arguments with respect to claims 90-97 and 110-115 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

- 17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vlacancich (5,529,494) teaches a screw-type dental implant and an installation tool.
- 18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo Primary Examiner

Juhan W. Woo

September 13, 2004